Specification

Please amend the specification as follows:

At page 1, amend fourth paragraph:

A typical known formulation for tibolone is a 100 mg dosage unit having ~~2.5~~ 2.5 mg of tibolone contained therein, a relatively small amount (e.g. approximately 1% by weight) of pharmaceutically acceptable auxiliaries, and a carrier making up the body of the tablet. The carrier typically is composed of 10% by weight of starch, e.g. potato starch, and 90% by weight of lactose, optionally with other non-starch ingredients such as amylopectin (see, e.g., US 4,701,450) or special types of cellulose, such as microcrystalline celluloses like Avicel (see, e.g., EP 707 848).

At page 2, amend third paragraph:

The dosage units of the invention not only provide substantively better stability as such, but, moreover, they surprisingly provide the possibility to incorporate a lower amount of tibolone. The customary amount of tibolone in the known dosage unit is 2.5 mg in tablets or capsules of 100 mg, i.e. 2.5%. For the sake of providing therapies better tailored to the individual woman's needs, it is desired to provide dosage units having a lower amount. However, if a known formulation with 10% of starch is adapted by simply including a lower amount of tibolone, the stability of the dosage unit is substantially decreased. E.g., if a 2.5 mg tibolone dosage unit has a shelf-life of, e.g., 2-3 years at room temperature, the same unit upon lowering the amount of tibolone to e.g. 0.3 mg can only be kept at 4°C for a period of 6-12 months. Such a lower stability being unacceptable in daily practice, it is a great advantage of the present invention that tibolone dosage units can be provided which have a low tibolone content, i.e. 2% by weight or less and, preferably, 1% by weight or less, and yet display sufficient stability. This advantage ~~being~~ is ~~manifest~~ manifested particularly if the starch content in the carrier is at least 40 % by weight, higher contents are preferred. The content of the

starch product more preferably is at least 50% by weight, and most preferably of from 90 to 100% by weight. As particularly upon using lower amounts of tibolone higher polysaccharide contents are preferred, the ratio of the weight percentage of tibolone and the starch percentage in the carrier plays a role in the present invention. Preferably, this ratio is at most 0.02.